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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

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| Application Number | 40/529,8 (371 of PCT/DI/00) |
| Filing Date | International Applic: Sept. 26, 20 |
| First Named Inventor | Jesper M. Ha |
| Group Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 0267us310 |

Total Number of Pages in This Submission

9

ENCLOSURES (check all that apply)

- ☐ Fee Transmittal Form
- ☐ Fee Attached
- ☐ Amendment / Response
- ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☒ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
- ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53

- ☐ Assignment Papers (for an Application)
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Small Entity Statement
- ☐ Request for Refund

- ☐ After Allowance Comm to Group
- ☐ Appeal Communication to of Appeals and Interferer
- ☐ Appeal Communication to (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Additional Enclosure(s) (please identify below):

- Form PTO/SB/08A-B (6 pp.)
- 66 cited references (refs. AQ-DD)
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Remarks

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| Firm or Individual name | Joanne R. Petithory Maxygen, Inc. Reg. No. 42,995 |
| Signature | <i>Joanne R. Petithory</i> |
| Date | Dec 28, 2005 |

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On: 12/28/2005

By: Ann Massey
Ann Massey

Attorney Docket No: 0267us310

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Jesper M. Haaning, *et al.*

Examiner:

Application No.: 10/529,624
(371 of PCT/DK03/00632)

Art Unit:

International Application Filed:
September 26, 2003
(371(c) date not yet established)

For: FVII or FVIIa Variants Having Increased
Coagulation Activity

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 CFR § 1.97
AND § 1.98**

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The references cited on the attached form PTO/SB/08A-B are being called to the attention of the Examiner. Copies of cited references AQ-DD are enclosed. Since the international application was filed after June 30, 2003, copies of the cited US patents and US published applications (references AA-AP) are not provided herein, pursuant to MPEP § 609 III A(2).

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no

J.M. Haaning, *et al.*

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Application No.: 10/529,624 (371 of PCT/DK03/00632)

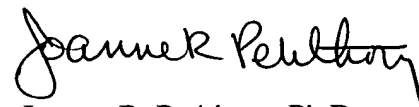
Information Disclosure Statement, page 2 of 2

representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

It is believed that no fee is required for submission of this statement, since it is being submitted prior to the first Office Action on the merits. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 50-0990. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

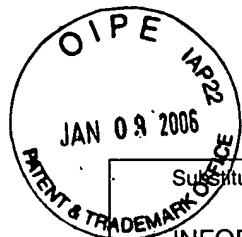
Respectfully submitted,

December 28, 2005



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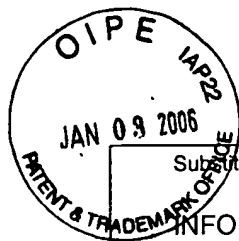
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| Substitute for form 1449A-B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | Complete if Known | |
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| | First Named Inventor | J.M. Haaning |
| | Group Art Unit | |
| | Examiner Name | |
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| U.S. PATENT DOCUMENTS | | | | | | |
|-----------------------|-------------|----------------------|-------------------------|--|--|---|
| Examiner Initials | Cite No. | U.S. Patent Document | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM/DD/YYYY | Pages, Columns, lines, Where Relevant Passages or Relevant Figures Appeal |
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| Examiner Initials | Cite No. | Foreign Patent Document | | | Name of Patentee or Applicant of Cited Document | Date of Publication of Cited Document MM/DD/YYYY | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | T |
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| Examiner Initials | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T |
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| | First Named Inventor | J.M. Haaning |
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| | Examiner Name | |
| | Attorney Docket Number | 0267us310 |

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| CB | Dickinson, C.D., <i>et al.</i> , "Identification of surface residues mediating tissue factor binding and catalytic function of the serine protease factor VIIa," <i>Proc. Natl. Acad. Sci. USA</i> 93:14379-14384 (1996). |
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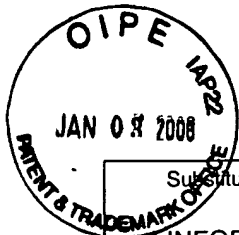


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| CM | Kemball-Cook, G., <i>et al.</i> , "Coagulation Factor VII Gln ¹⁰⁰ Arg—Amino Acid Substitution at the Epidermal Growth Factor 2-Protease Domain Interface Results in Severely Reduced Tissue Factor Binding and Procoagulant Function," <i>J. Biological Chemistry</i> 273(14):8516-8521 (1998). |
| CN | Leonard, B.J.N., <i>et al.</i> , "Activation and Active Site Occupation Alter Conformation in the Region of the First Epidermal Growth Factor-like Domain of Human Factor VII," <i>J. Biological Chemistry</i> 275(45):34894-34900 (2000). |
| CO | Mayer, S.A. "Ultra-early hemostatic therapy for intracerebral hemorrhage," <i>Stroke</i> 34(1):224-229 (2003). |
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| CS | Persson, E., "Characterization of the interaction between the light chain of factor VIIa and tissue factor," <i>FEBS Letters</i> 413:359-363 (1997). |
| CT | Persson, E., <i>et al.</i> , "Ca ²⁺ Binding to the First Epidermal Growth Factor-like Domain of Factor VIIa Increases Amidolytic Activity and Tissue Factor Affinity," <i>J. Biological Chemistry</i> 272(32):19919-19924 (1997). |
| CU | Petersen, L.C., <i>et al.</i> , "Binding of Zn ²⁺ to a Ca ²⁺ loop allosterically attenuates the activity of factor VIIa and reduces its affinity for tissue factor," <i>Protein Science</i> 9:859-866 (2000). |
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| CW | Petrovan, R.J., <i>et al.</i> , "Residue Met(156) contributes to the labile enzyme conformation of coagulation factor VIIa" <i>J. Biol. Chem.</i> 276(9):6616-6620 (2001). |

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| | CX | Ruf, W., <i>et al.</i> , "Importance of Factor VIIa Gla-Domain Residue Arg-36 for Recognition of the Macromolecular Substrate Factor X Gla-Domain," <i>Biochemistry</i> 38:1957-1966 (1999) | |
| | CY | Shah, A.M., <i>et al.</i> , "Manipulation of the membrane binding site of vitamin K-dependent proteins: Enhanced biological function of human factor VII," <i>Proc. Natl. Acad. Sci. USA</i> 95:4229-4234 (1998). | |
| | CZ | Shobe, J., <i>et al.</i> , "Macromolecular Substrate Affinity for the Tissue Factor-Factor VIIa Complex is Independent of Scissile Bond Docking," <i>J. Biological Chemistry</i> 274(34):24171-24175 (1999). | |
| | DA | Shobe, J., <i>et al.</i> , "Regulation of the Catalytic Function of Coagulation Factor VIIa by a Conformational Linkage of Surface Residue Glu 154 to the Active Site," <i>Biochemistry</i> 38:2745-2751 (1999). | |
| | DB | Sorensen, B.B. <i>et al.</i> "Incorporation of an active site inhibitor in factor VIIa alters the affinity for tissue factor," <i>J. Biol. Chem.</i> 272(18):11863-11868 (1997). | |
| | DC | Sridhara S. <i>et al.</i> "Activation of a recombinant human factor VII structural analogue alters its affinity of binding to tissue factor," <i>Am. J. Hematol.</i> 53(2):66-71 (1996). | |
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